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INFORMATION DISCLOSURE **STATEMENT**

Examining Group 1632

Patent Application

Qocket No. USF-182XC1

Arial No. 10/655,873

Alexandria, VA 22313-1450 February

FEB 1 7 2004

Glenn P. Ladwig, Patent Attorney

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

TRADEN

Art Unit

1632

Applicants

Shyam S. Mohapatra, Mukesh Kumar

Serial No.

10/655,873

Filed

September 5, 2003

For

Genetic Adjuvants for Immunotherapy

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT <u>UNDER 37 CFR §§1.97 AND 1.98</u>

Sir:

In accordance with 37 CFR §1.56, the references listed on the attached form PTO/SB/08 are being brought to the attention of the examiner for consideration in connection with the examination of the above-identified patent application. A copy of each cited reference is enclosed.

The applicants respectfully assert that the substantive provisions of 37 CFR §§1.97 and 1.98 are met by the foregoing statement.

Respectfully submitted,

Glenn P. Ladwig

Patent Attorney

Registration No. 46,853

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Attachments: Form PTO/SB/08 (5 pages); copies of references cited therein.

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PTO/SB/08A (08-03) Approved for use through 07/31/2006. OMB 0651-0031

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Complete if Known Substitute for form 1449A/PTO **Application Number** 10/655,873 INFORMATION DISCLOSURE Filing Date September 5, 2003 STATEMENT BY APPLICANT **First Named Inventor** Shyam S. Mohapatra (use as many sheets as necessary) **Art Unit** 1632 **Examiner Name Attorney Docket Number** of Sheet 5 **USF-182XC1**

	U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. 1	Document Number Number - Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	
	U1	US-6,489,306 B2	12-03-2002	Mohapatra et al.	All	
	U2	US-2003/0198624 A1	10-23-2003	Mohapatra et al.	All	
	U3	US-2001/0006951 A1	07-05-2001	Mohapatra et al.	All	
	U4	US-				
	U5	US-				
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		FOREIGN	PATENT DOCU	JMENTS		
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Examiner Initials*		Country Code ³ - Number ⁴ - Kind Code ⁵ (if known)				T ⁶
	F1	WO 03/074561 A1	09-12-2003	Univ. South Florida	All	
	F2					
	F3					
	F4					
	F5					
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	F7					

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Sheet 2 of

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Application Number	10/655,873			
Filing Date	September 5, 2003			
First Named Inventor	Shyam S. Mohapatra			
Group Art Unit	1632			
Examiner Name				
Attorney Docket Number	USF-182XC1			

		NON PATENT LITERATURE DOCUMENTS	
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	R1	BARNES, P.J. "Cytokine-directed therapies for asthma" J. Allergy Clin. Immunol., 2001, 108:S72-76.	
	R2	BEHERA, A.K. et al. "Adenovirus-mediated interferon y gene therapy for allergic asthma: involvement of interleukin 12 and STAT4 signaling" <i>Human Gene Therapy</i> , 2002, 13:1697-1709.	
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	R5	CHEN, Q. et al. "Development of Th-1-type immune responses requires the type I cytokine receptor TCCR" Nature, 2000, 407:916-920.	
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	R9	FORD, J.G. et al. "IL-13 and IFN-y: interactions in lung inflammation" J. Immunol., 2001, 167:1769-1777.	
	R10	GAVETT, S.H. et al. "Interleukin 12 inhibits antigen-induced airway hyperresponsiveness, inflammation, and Th2 cytokine expression in mice" J. Exp. Med., 1995, 182:1527-1536.	
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, , , , , , , ,	R12	HANSEN, G. et al. "Allergen-specific Th1 cells fail to counterbalance Th2 cell-induced airway hyperreactivity but cause severe airway inflammation" J. Clin. Invest., 1999, 103:175-183.	
	R13	HANSEN, G. et al. "CD4 [*] T helper cells engineered to produce latent TGF-β1 reverse allergen-induced airway hyperreactivity and inflammation" J. Clin. Invest., 2000, 105:61-70.	;

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Signature	Considered	

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Complete if Known		
Application Number	10/655,873	
Filing Date	September 5, 2003	
First Named Inventor	Shyam S. Mohapatra	
Group Art Unit	1632	
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		NON PATENT LITERATURE DOCUMENTS	
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	R14	HASBOLD, J. et al. "Integrating signals from IFN-y and IL-4 by B cells: positive and negative effects on CD40 ligand-induced proliferation, survival, and division-linked isotype switching to IgG1, IgE, and IgG2a" J. Immunol., 1999, 163:4175-4181.	
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	R16	HE, T-C. et al. "A simplified system for generating recombinant adenoviruses" Proc. Natl. Acad. Sci. USA, 1998, 95:2509-2514.	
	R17	KAPLAN, M.H. et al. "Impaired IL-12 responses and enhanced development of Th2 cells in Stat4-deficient mice" Nature, 1996, 382:174-177.	
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	R23	LACK, G. et al. "Nebulized but not parenteral IFN-y decreases IgE production and normalizes airways function in a murine model of allergen sensitization" J. Immunol., 1994, 152:2546-2554.	
	R24	LI, X-M. et al. "Mucosal IFN-y gene transfer inhibits pulmonary allergic responses in mice" J. Immunol., 1996, 157:3216-3219.	
	R25	LIGHVANI, A.A. et al. "T-bet is rapidly induced by interferon-y in lymphoid and myeloid cells" PNAS, 2001, 98(26):15137-15142.	
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Application Number	10/655,873	
Filing Date	September 5, 2003	
First Named Inventor	Shyam S. Mohapatra	
Group Art Unit	1632	
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Attorney Docket Number	USF-182XC1	

		NON PATENT LITERATURE DOCUMENTS	
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	R27	MINSHALL, E.M. et al. "Eosinophil-associated TGF-β ₁ mRNA expression and airways fibrosis in bronchial asthma" <i>Am. J. Respir. Cell Mol. Biol.</i> , 1997, 17:326-333.	
	R28	MORRISON, D.F. and MURTAUGH, M.P. "Adenovirus-mediated expression of interleukin-1 receptor antagonist in swine cells in vitro and in vivo" <i>Veterinary Immunol. and Immunopatholgy</i> , 2001, 78:71-81.	
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	R31	O'GARRA, A. and ARAI, N. "The molecular basis of T helper 1 and T helper 2 cell differentiation" Cell Biol., 2000, 10:542-550.	
	R32	OPPMANN, B. et al. "Novel p19 protein engages IL-12p40 to form a cytokine, IL-23, with biological activities similar as well as distinct from IL-12" Immunity, 2000, 13:715-725.	
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	R34	RANDOLPH, D.A. et al. "Modulation of airway inflammation by passive transfer of allergen-specific Th1 and Th2 cells in a mouse model of asthma" J. Immunol., 1999, 162:2375-2383.	
	R35	ROBINSON, D.S. et al. "Predominant T _{H2} -like bronchoalveolar T-lymphocyte population in atopic asthma" N. Engl. J. Med., 1992, 326:298-304.	
	R36	RUDICK, R.A. et al. "Management of multiple sclerosis" J. Engl. J. Med., 1997, 337(22):1604-1611.	
	R37	SCHWARZE, J. et al. "Local treatment with IL-12 is an effective inhibitor of airway hyperresponsiveness and lung eosinophilia after airway challenge in sensitized mice" J. Allergy Clin. Immunol., 1998, 102:86-93.	
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	R39	STIRLING, R.G. and CHUNG, K.F. "New immunological approaches and cytokine targets in asthma and allergy" <i>Eur. Respir. J.</i> , 2000, 16:1158-1174.	

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	R40	SUR, S. et al. "Mucosal IL-12 inhibits airway reactivity to methacholine and respiratory failure in murine asthma" Exp. Lung Res., 2000, 26:477-489.	
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	R49		
	R50		
	R51		
	R52		

Examiner	Date
Signature	 Considered

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